

Application No.: 10/044,441

Case No.: 57287US002

REMARKS

Claims 1 and 6 have been amended. Claims 1 to 8 remain pending and are submitted for examination.

Claim Objections

Claim 1 was objected to of the presence of the word "and" which the Office Action identifies as being on line 6 of claim 1. Applicant's amended claim 1, set forth above, includes the requested amendment. Therefore, the objection to this informality is believed to be moot.

§102 Rejections

Claims 1 and 3 stand rejected under 35 USC § 102(b) as being anticipated by Kirckoff (US 6,488,890). According to the Office Action, Kirckoff is said to each and every element of the present invention, as set forth in claims 1 and 3. Kirckoff describes a sterilization indicator for monitoring the effectiveness of a sterilization process. The indicator described by Kirckoff is a fairly sophisticated sterilization indicator and a monitoring method that allows the user to acquire, store and use sterilization monitoring information quickly and cost efficiently, reduce sterile product hold time, increase the accuracy of information storage and data management, and the like (see col. 4, line 66 through col. 5, line 10). In addition to an indicator, the Kirckoff invention provides a scanning means which may be provided as a code reader such as a bar coder reader (see col. 7, lines 39-40; col. 15, lines 7-21). Figure 17 illustrates what Kirckoff describes a preferred embodiment of a scanning means which can include an illumination source, 82, a controller/processor 81, a detector 83, and an output component 84. The output component 84 may be in the form of display lights, computer displays, or graphical user interfaces. While the scanning means can be a code reader, Kirckoff clearly contemplates a more complex scanning means within the scope of his invention, and Kirckoff's scanning means requires an external computer or processor for the retention, for example, of reference spectral curves, and having the ability in some

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embodiments to compare the sample spectral curve with the reference curves to find a best fit (see col. 17, line 61 through col. 18, line 62).

Nothing in Kirckoff can be said to teach or suggest the system of the present invention. Nothing in Kirckoff teaches or suggests a system for determining the efficacy of a sterilization process wherein the system communicates that determination to a remote location, and wherein the system comprises a sterilization sensor comprising an indicator that undergoes an optical change when exposed to an efficacious sterilization process, and a reader adapted to receive the sterilization sensor and wherein the reader (with the sensor retained therein) is adapted for inclusion within packs of goods to be sterilized and is capable of withstanding sterilizing conditions multiple times and through multiple uses.

For at least the foregoing reasons, Kirckoff does not teach each and every element of the present invention, as set forth in the pending claims 1 and 3. Accordingly, Applicant now requests the withdrawal of the Office's §102 rejection of claim 1 and 3.

§103 Rejections

Claims 2, 4 and 5 were rejected under 35 USC §103(a) as being unpatentable over Kirckoff. Applicant notes that claims 2, 4 and 5 are dependent from claim 1. For the reasons set forth above, claim 1 is believed to be allowable over Kirckoff. Consequently, dependent claims 2, 4 and 5 are also believed to be allowable based on their status as depending from claim 1. The withdrawal of this rejection is now requested.

Method claims 6-8 were rejected under 35 USC §103(a) as being unpatentable over Joslyn (US 3,982,893) in view of Kirckoff. Joslyn describes an apparatus comprising sensor elements and a radio transmitter capable of continuously monitoring a sterilization affecting environmental condition such as the concentration of the sterilizing gas or the temperature of the environment to which the sensor is exposed (see, e.g., col. 3, lines 4-11). Joslyn provides a an active monitor for continuously monitoring environmental conditions occurring within a

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sterilization chamber and transmits the information to a controller which can make any necessary changes to bring the sterilization conditions back to within their optimum conditions. Nothing in Joslyn teaches or suggests the passive monitoring method of the present invention which comprises placing a sterilization sensor in a reader and the reader within a package of goods, subjecting the package to sterilization and thereafter interrogating the reader to determine whether an optical change has occurred on the indicator without opening the package. The present invention specifically describes and claims a passive indicator system and a use thereof wherein the system is adapted for inclusion within packs of goods to be sterilized, exhibits a chemical resistance capable of withstanding sterilizing conditions multiple times and through multiple uses and which provides a color change that can be read remotely. Moreover, the teachings of Kirckoff do not make up for the deficiencies of Joslyn. As noted, Kirckoff does not teach or suggest the inclusion of an indicator within the reader and Kirckoff's sophisticated equipment contemplates a processor capable of performing multiple tasks and functions but not suited for the inclusion within the package of goods to be sterilized.

Applicant has endeavored to address all of the issues raised in the recent Office Action. It is believed that the pending claims are in condition for allowance, and the allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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